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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/529,397

**Applicant(s)**

CHRISTENSEN ET AL.

**Examiner**

AMBER D. STEELE

**Art Unit**

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-40, 42-102 and 106-111 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 13-16, 21-23, 27-31 and 43-102 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 9/10/08 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-846)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-102 were originally filed on March 28, 2005.

A preliminary amendment received on January 27, 2006 amended claims 1-32, 38, 40-43, 46, 48, 49, 53, 55-62, 64-75, 77, 79, 81, 83-86, 91, 93, and 96-101.

The amendment to the claims received on September 10, 2008 canceled claims 1 and 41, amended claims 2-32, 38, 46, 49, 53, 60, 75, 79, and 85, and added new claims 103-105.

The amendment to the claims received on January 8, 2009 canceled claims 103-105.

The amendment to the claims received on February 17, 2010 amended claims 21-23, 25, 27-32, 49, and 53 and added new claims 106-111. Please note: the claim set received on February 17, 2010 contains claims without proper status identifiers (see claims 19 - also see the objection to the claim below; see withdrawn claims 21-23 and 27-31). While applicants asserted in the reply filed on February 17, 2010 (see page 21, last paragraph) that the status identifiers were changed to "withdrawn", the claim amendment received on February 17, 2010 has status identifiers of "currently amended" for present claims 21-23 and 27-31.

Claims 2-40, 43-102, and 106-111 are currently pending.

Claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 are currently under consideration.

### ***Election/Restrictions***

2. Applicants elected, with traverse, Group II (previous claims 32-42; please note: Group I, previous claims 2-31, is rejoined due to the claim amendments received on September 10, 2008 and the petition decision mailed on May 15, 2009) in the reply filed on January 17, 2008. Claims

21-23, 27-31, and 43-102 are withdrawn from further consideration pursuant to 37 CFR

1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim.

3. Applicants elected, with traverse, the species of at least  $10^2$  beads, the species of monodisperse as the species of dispersion, essentially spherical as the species of particle shape, 4 to 10 particles as the species of number of particles, essentially the same diameter as the species of diameter, spectroscopically detectable marker as the species of marker, probing with frequencies as the species of detection, and optically transparent as the species of polymer in the reply filed on January 17, 2008 is acknowledged. Claims 4-6 and 13-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

Please note: in the petition decision mailed on May 15, 2009, QAS Julie Burke and authorized by acting Director Michael Wityshyn clearly state on the record that the species of marker, detection, and polymer are all obvious variants of each other. Therefore, any species listed or found in the art for one species is an obvious variant of another species for all claimed markers, forms of detection, and polymers. If applicants disagree, applicants are respectfully requested to state the reasons for disagreeing clearly on the record which may result in withdrawal of claims to nonelected species.

*Arguments and Response*

4. Applicants contend that the species of particle number per bead is an important limitation in distinguishing the art of record and because of “correspondence problems” (see pages 23-25 of the present specification). This is not found persuasive because the correspondence problems are related to the method of utilizing the beads and not the structure of the beads.

*Potential for Rejoinder*

5. Applicants elected claims directed to the product. If a product claim is subsequently found allowable, withdrawn process claims that **depend from or otherwise include all the limitations of the allowable product claim** will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re*

*Ochiai, In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, **in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to a rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

***Priority***

6. The present application claims status as a National Stage (i.e. 371) of PCT/DK03/00635 filed on September 26, 2003 which claims benefit of U.S. provisional applications 60/482,453 filed on June 26, 2003 and 60/413,771 filed September 27, 2002. In addition, the present application claims foreign priority to PA 2003 00969 filed June 26, 2003 and PA 2002 01444 filed September 27, 2002. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

7. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed applications, provisional Application Nos. 60/413,771 and 60/482,453 and foreign applications PA 2002 01444 and PA 2003 00969, fail to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The limitations of independent claim 32 and all dependent claims thereof. Therefore, the claims have a priority date of September 26, 2003 (i.e. filing date PCT/DK03/00635).

#### ***Arguments and Response***

8. Applicants contend that since the present application is a 371 (National Stage) of PCT/DK03/00635 (i.e. has the same specification), that the presently claimed invention must have priority to PCT/DK03/00635. Applicants also contend that at least claims 19 and 20 are entitled to the benefit of DK PA200201444 and U.S. provisional application 60/413,771.

Applicants' arguments are not found persuasive, in part. After clarification that claims 1-119 were the original claims for PCT/DK03/00635 and claims 1-102 were the amended claims (i.e. original claim 91 of PCT/DK03/00635 contains the limitation "wherein the diameter of the particles is preferably less than 30 micrometer"), the priority of the presently claimed invention to PCT/DK03/00635 is noted. However, the priority to the U.S. provisional applications and the foreign applications is not supported by the disclosures for independent claim 32 and all dependent claims thereof.

#### ***Invention as Claimed***

9. A composition comprising a plurality of different, spatially encoded beads, wherein essentially each bead is individually identifiable, wherein each bead has a diameter of from 0.5 millimeter to less than 2.0 millimeter, and comprises from 3 to not more than 10 spatially

immobilized, individually detectable particles held in a polymer matrix, wherein the diameter of the particles is less than 30 micrometer and variations thereof.

10. Regarding what the composition is “suitable for” (see claim 106) and how each bead can be “identified” (see claims 109-111), the limitations are considered intended use limitations (see MPEP § 2112 and § 2106). Regarding the product-by-process limitation of present claim 108, applicants are respectfully directed to MPEP § 2113.

**Withdrawn Objection**

11. The objection to claim 32 and all dependent claims thereof is withdrawn in view of the claim amendment received on February 17, 2010.

**New Objection**

***Claim Objections***

12. Claim 19 is objected to because of the following informalities: present claim 19 has a status identifier of “currently amended”. However, an amendment to the claim is not present. Appropriate correction is required.

**Maintained Objections**

***Claim Objections***

13. Claim 19 is objected to because of the following informalities: the claim contains improper Markush language. See MPEP § 2173.05(h). Appropriate correction is required.



***Arguments and Response***

14. Applicants contend that claim 19 was amended to correct the improper Markush language. However, claim 19 while having a status identifier of “currently amended” does not actually contain any amendments (see claim amendment received on February 17, 2010).

15. Claim 20 is objected to because of the following informalities: the claim contains improper Markush language. See MPEP § 2173.05(h). Appropriate correction is required.

***Arguments and Response***

16. Applicants contend that claim 20 was amended to correct the improper Markush language. However, claim 20 was not amended in the amendment received on February 17, 2010.

17. Claim 25 is objected to because of the following informalities: the claim contains inadequate punctuation (i.e. commas missing). Appropriate correction is required.

***Arguments and Response***

18. Applicants contend that claim 25 was amended to correct the inadequate punctuation. However, claim 25 still requires a comma between polyacrylamides and polyacrylamides.

***Withdrawn Rejections***

19. The rejection of claims 2, 3, 7-12, 17-40, and 42 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement (new matter) is withdrawn in view of the support pointed out in original claim 91 (i.e. the 1-119 claim set originally filed in PCT/DK03/00635).

20. The rejection of claims 2, 3, 7-12, 17-20, 24-26, 32-40, and 42 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the definitions provided on pages 15-16 of the present specification regarding “essentially”.

**New Rejections Necessitated by Amendment**

***Claim Rejections - 35 USC § 112***

21. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

22. Claims 106-111 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Applicants have neglected to point out support for new claims 106-111 in the originally filed specification. Applicant should specifically point out the support for any amendments made to the disclosure.

**Maintained Rejections**

***Claim Rejections - 35 USC § 112***

23. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

24. Claim 19 contains the trademark/trade name Alexa™ and Dapoxyl™. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe markers and, accordingly, the identification/description is indefinite.

#### *Arguments and Response*

25. Applicants' arguments directed to the rejection under 35 USC 112, second paragraph (indefinite), for claim 19 were considered but are not persuasive for the following reasons.

Applicants contend that the holding by the Board in *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982) does not support the rejection and that "applicants have not urged that the trademarked products recited in claim 19 be interpreted as referring to anything other than the products to which those trademarks were applied".

Applicants' arguments are not convincing since trademarks are not products per se but rather an identification of a source or origin of a product. See MPEP § 2173.05(u). If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular

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material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

***Claim Rejections - 35 USC § 102***

26. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

27. Claims 2, 3, 7-12, 17-20, 24-26, 32, 38-40, 42, and 106-111 are rejected under 35 U.S.C. 102(b) as anticipated by Trau et al. WO 99/24458 published May 20, 1999 (provided by applicants in the IDS).

For present claims 2, 3, 7-12, 17-20, 24-26, 32, 38-40, 42, and 106-111 Trau et al. teach compositions comprising polymer carriers (i.e. beads) wherein each polymer carrier has a diameter of 1-1000  $\mu\text{m}$  (i.e. 0.5 mm to 2 mm) and comprises at least one reporter bead (i.e. essentially spherical) or microparticle (i.e. 3 to 10) spatially immobilized wherein the reporter bead or microparticle is 0.01 to 50  $\mu\text{m}$  in diameter and contains fluorescent markers (see fluorescent markers incorporated by reference on pages 17 and 18) and wherein the carrier contains linkers (i.e. reactive group or scaffold) to attach oligos (bioactive species) (please refer to the entire specification particularly the abstract; pages 6-12, 15-19, 23-24, 27-28; Examples; Figures 6-14).

Therefore, the teachings of Trau et al. anticipate the presently claimed method.

*Arguments and Response*

28. Applicants' arguments directed to the rejection under 35 USC 102 (b) as being anticipated by Trau et al. for claims 2, 3, 7-12, 17-20, 24-26, 32, 38-40, 42, and 106-111 were considered but are not persuasive for the following reasons.

Applicants contend that Trau et al. do not teach "from 3 to not more than 10 spatially immobilized, individually detectable particles held in a polymer matrix". Applicants point to Figures 6-8 of Trau et al. Applicants also contend that the definition of "individually identifiable" in the present specification and recited in present independent claim 32 distinguish the presently claimed invention from Trau et al. Applicant's also contemplate hypothetical methods that will not be addressed since these methods are not based in factual evidence, but are speculative in nature (i.e. the arguments of counsel cannot take the place of evidence in the record). In addition, applicants contend that the present invention discloses "particles that generally speaking are embedded in the beads" (i.e. inside) while Trau et al. disclose particles attached to the surface of the beads (applicants point to the present specification at pages 15, 17, 18 which refer to "particles within the encoded bead", "particles in the bead", methods of making the beads). Applicants also contend that while Trau et al. teach "reporter beads may be attached to the surface of a carrier" or "attach reporter beads to the inside of a carrier through existing pores of the carrier", this disclosure is not enabled (it is noted that applicants neglected to provide factual evidence to support this conclusion).

Applicants' arguments are not convincing since the teachings of Trau et al. anticipate the composition of the instant claims. Trau et al. teach a carrier having one or more reporter beads

(i.e. includes presently claimed range of 3 to 10 particles per bead) noncovalently attached thereto, each molecule is attached to a respective carrier and wherein there is also provided a plurality of reporter beads attached to the carrier and/or to adjacent reporter beads in non-covalent manner characterized in that each reporter bead has a marker associated therewith to identify the chemical group attached to the carrier as well as to identify the position in sequence of the chemical group relative to other chemical groups in each molecule whereby each molecule in the library will have a unique signal associated therewith which signal is dependent on different combinations of markers to facilitate direct identification of each molecule (i.e. individually identifiable), detection of the dye (e.g. fluorophore) combination with a fluorescence microscope to observe individual reporter beads, and attachment of reporter beads to the inside of a carrier through existing pores of the carrier (please refer to the entire specification particularly the abstract; pages 6-8, 26-28). See MPEP § 2123. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." See *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) and *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968). Therefore, while the "preferred embodiments" taught by Trau et al. in Figures 6-8 teach more than 10 particles and only 4 different colors, the disclosure of Trau et al. teach utilization of less than 10 particles and utilization of various fluorophores, etc. (i.e. more than four colors; see pages 17-18).

The arguments of counsel cannot take the place of evidence in the record.

***Claim Rejections - 35 USC § 103***

29. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

30. Claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trau et al. WO 99/24458 published May 20, 1999 (provided by applicants in the IDS) and Frankel U.S. Patent 6,506,342 (issued January 14, 2003; filed May 15, 2000; effective filing date of June 19, 1997).

For present claims 2, 3, 7-12, 17-32, 38-40, 42, and 106-111 Trau et al. teach compositions comprising polymer carriers (i.e. beads) wherein each polymer carrier has a diameter of 1-1000  $\mu\text{m}$  (i.e. 0.5 mm to 2 mm) and comprises at least one reporter bead (i.e. essentially spherical) or microparticle (i.e. 3 to 10) spatially immobilized wherein the reporter bead or microparticle is 0.01 to 50  $\mu\text{m}$  in diameter and contains fluorescent markers (see fluorescent markers incorporated by reference on pages 17 and 18) and wherein the carrier contains linkers (i.e. reactive group or scaffold) to attach oligos (bioactive species) (please refer to the entire specification particularly the abstract; pages 6-12, 15-19, 23-24, 27-28; Examples; Figures 6-14).

However, Trau et al. does not teach a specific number of carriers.

For present claims 33-37, Frankel teaches bead libraries comprising  $10^2$ - $10^6$  beads, greater than  $10^8$  beads, or greater than  $10^9$  beads (see the entire specification particularly columns 2 and 9).

The claims would have been obvious because the substitution of one known element (i.e. carrier population of unknown size taught by Trau et al.) for another (i.e. bead library of greater than  $10^9$  beads as taught by Frankel) would have yielded predictable results (e.g. large library size, more specifically identifiable beads, etc.) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

#### ***Arguments and Response***

31. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Trau et al. and Frankel for claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 were considered but are not persuasive for the following reasons.

Applicants contend that Trau et al. does not teach the "particles-per-bead limitation" of present claim 32 and that Frankel does not teach particles having a diameter of less than 30 micrometers.

Applicants' arguments are not convincing since the teachings of Trau et al. and Frankel render the composition of the instant claims *prima facie* obvious.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).



Trau et al. teach a carrier having one or more reporter beads (i.e. includes presently claimed range of 3 to 10 particles per bead) noncovalently attached thereto (please refer to the entire specification particularly the abstract; pages 6-8). See MPEP § 2123. "The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." See *In re Heck*, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) and *In re Lemelson*, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968). Therefore, while the "preferred embodiments" taught by Trau et al. in Figures 6-8 teach more than 10 particles, the disclosure of Trau et al. teach utilization of less than 10 particles. In addition, Frankel is utilized to teach the number of products in the composition and not the particular structure of each product in the composition (see Trau et al. regarding the particular structure of each product in the composition).

32. Claims 7, 8, 10, 11, 25, 26, 32, 38-40, 42, and 106-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nilsson et al. U.S. Patent 5,015,576 issued May 14, 1991.

For present claims 7, 8, 10, 11, 25, 26, 32, 38-40, and 42, Nilsson et al. teach particles or macroporous beads which enclose cavities comprising water-insoluble solid, liquid, gaseous cavity generating compound, or cells (i.e. particles) wherein the size of each particle is 10 to 5000  $\mu\text{m}$  and 5-10 cells per bead, the diameter of the cavities are 1 to 50  $\mu\text{m}$ , the polymer utilized is polyacrylamide, and the cavities can be coated with fibronectin, etc. (reactive group or scaffold) to attach the cells (i.e. bioactive species; please refer to the entire specification particularly the abstract; column 3; Examples).

The claims would have been obvious because the substitution of one known element (i.e. specific number of particles or specific polymer taught by Nilsson et al.) for another (i.e. specific number of particles, another polymer; see petition decision by Julie Burke wherein QAS Burke stated that all polymers would be obvious variants) would have yielded predictable results (e.g. specific number of particles per bead, specific polymer utilized to produce beads) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

#### *Arguments and Response*

33. Applicants' arguments directed to the rejection under 35 USC 103 (a) as being unpatentable over Nilsson et al. for claims 7, 8, 10, 11, 25, 26, 32, 38-40, 42, and 106-111 were considered but are not persuasive for the following reasons.

Applicants contend that Nilsson et al. does not teach the specific number of particles per bead or beads with a diameter of 0.5 mm to less than 2 mm. Applicants assert that Nilsson et al. teach beads between 10 and 500  $\mu\text{m}$  and that each bead can be provided with 5-10 cells/bead (Example 9). Applicants also discuss correspondence problems regarding the number of particles per bead.

Applicants' arguments are not convincing since the teachings of Nilsson et al. render the composition of the instant claims *prima facie* obvious. Nilsson et al. teach beads with diameters of 10 to 5000  $\mu\text{m}$  (i.e. 0.01-5 mm which encompasses the range of from 0.5 mm to 2 mm) and 5-10 cells/bead (please refer to the entire specification particularly column 3; Example 9). Furthermore, the "correspondence problems" are directed toward the method of utilizing the beads and not the structure of the beads.

### ***Double Patenting***

34. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

35. Claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-10 and 59 of copending Application No. 11/631,181. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. application 11/631,181 are drawn to a composition of spatially encoded beads.

For present claims 32 and 41, U.S. application 11/631,181 claims a composition comprising a plurality of spherical beads with a radiofrequency chip embedded wherein essentially each of said beads is individually identifiable (please refer to claim 3).

For present claims 38-40, U.S. application 11/631,181 claims hydrophilic moieties (i.e. functionalisation site), surface polyethers, surface polyvinyls, surface polyacrylates, surface

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polyacrylamides, polyacrylamides, surface polystyrenes, surface polycarbonates, surface polyesters, and surface polyamides (please refer to claims 4-6).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### *Arguments and Response*

36. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 11/631,181 for claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 were considered but are not persuasive for the following reasons.

Applicants request that the rejection be held in abeyance.

Applicants' arguments are not convincing since the claimed invention of 11/631,181 renders obvious the invention of the instant claims. In addition, while a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated, the present is a rejection (albeit a provisional rejection, still a "real" rejection) and will not be held in abeyance (see MPEP § 714.02). In addition, the definition of abeyance (i.e. temporary inactivity, cessation, or suspension) includes language to suggest a withdrawal of the rejection (even if the withdrawal would be temporary). For clarity of the record, the rejection will not be held in abeyance until patentable subject matter, if any, is determined.

37. Claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 94

and 96 of copending Application No. 10/566,757. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed invention and the invention as claimed in U.S. application 10/566,757 are drawn to a beaded polymer matrix comprising beads with a plurality of spatially immobilized particles.

For present claims 32 and 41, U.S. application 10/566,757 claims a beaded polymer matrix comprising beads with a plurality of spatially immobilized particles wherein each particle comprises at least one fluorescent dye compound and wherein each particle is individually detectable (please refer to claims 94 and 96).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### *Arguments and Response*

38. Applicants' arguments directed to the rejection on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 10/566,757 for claims 2, 3, 7-12, 17-20, 24-26, 32-40, 42, and 106-111 were considered but are not persuasive for the following reasons.

Applicants request that the rejection be held in abeyance.

Applicants' arguments are not convincing since the claimed invention of 10/566,757 renders obvious the invention of the instant claims. In addition, while a request may be made that objections or requirements as to form not necessary to further consideration of the claims be held in abeyance until allowable subject matter is indicated, the present is a rejection (albeit a provisional rejection, still a "real" rejection) and will not be held in abeyance (see MPEP § 714.02). In addition, the definition of abeyance (i.e. temporary inactivity, cessation, or

suspension) includes language to suggest a withdrawal of the rejection (even if the withdrawal would be temporary). For clarity of the record, the rejection will not be held in abeyance until patentable subject matter, if any, is determined.

***Conclusion***

39. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

40. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 4,994,312.

***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/  
Primary Examiner, Art Unit 1639